

103^D CONGRESS
2^D SESSION

H. R. 4151

To amend title 35, United States Code, to provide for the compulsory licensing of the patents for certain products which have not been commercially marketed or used.

IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 1994

Mr. NADLER introduced the following bill; which was referred to the
Committee on the Judiciary

A BILL

To amend title 35, United States Code, to provide for the compulsory licensing of the patents for certain products which have not been commercially marketed or used.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Essential Pharma-
5 ceuticals Act of 1994”.

6 **SEC. 2. COMPULSORY LICENSING OF PATENTS.**

7 (a) IN GENERAL.—Chapter 14 of title 35, United
8 States Code, is amended by adding at the end the
9 following:

1 **“§ 158. Compulsory licensing of certain patents**

2 “(a) DETERMINATION BY SECRETARY OF HEALTH
3 AND HUMAN SERVICES.—In any case in which the Sec-
4 retary of Health and Human Services determines, after
5 notice and an opportunity for an agency hearing, that—

6 “(1) the owner of a patent which—

7 “(A) claims a product, a method of using
8 a product, or a method of manufacturing a
9 product, and

10 “(B) may be extended under section 156 of
11 this title,

12 has not taken all reasonable steps toward the com-
13 mercial marketing or use of that product, if the
14 product is not already so marketed or used, and

15 “(2) the availability of the product to the public
16 is of vital importance to the public health or welfare,
17 the Secretary shall notify the Commissioner of the
18 Secretary’s determination.

19 “(b) COMPULSORY LICENSING OF PATENT.—

20 “(1) IN GENERAL.—Upon receiving a notifica-
21 tion from the Secretary of Health and Human Serv-
22 ices under subsection (a) with respect to a product,
23 the Commissioner shall provide for the compulsory
24 licensing of all patents relating to that product, in
25 accordance with this section.

1 “(2) REGULATIONS.—The Commissioner shall
2 issue regulations providing for the compulsory li-
3 censing of patents under this section. Such regula-
4 tions—

5 “(A) shall provide for—

6 “(i) the payment to the Commissioner
7 of fees for the use of any such patent, in
8 such manner and in such amounts as the
9 Commissioner may prescribe; and

10 “(ii) the distribution of such fees to
11 the patent holders, in such manner and at
12 such times as the Commissioner may pre-
13 scribe; and

14 “(B) may require the keeping of such
15 records, and the submission of such reports, as
16 the Commissioner considers necessary to carry
17 out this section.

18 “(c) APPEALS.—

19 “(1) TO BOARD OF PATENT APPEALS AND
20 INTERFERENCES.—Any person aggrieved by a deci-
21 sion of the Commissioner under this section may ap-
22 peal that decision to the Board of Patent Appeals
23 and Interferences, after having paid the fee for such
24 appeal.

1 “(2) TO COURT OF APPEALS FOR THE FEDERAL
2 CIRCUIT.—A person aggrieved by a decision of the
3 Board of Patent Appeals and Interferences under
4 paragraph (1) may appeal that decision to the Unit-
5 ed States Court of Appeals for the Federal Circuit.
6 The provisions of sections 142 and 143 of this title
7 shall apply to an appeal under this subsection to the
8 same extent as such sections apply to an appeal
9 under section 141 of this title.”

10 (b) CONFORMING AMENDMENTS.—(1) The table of
11 sections at the beginning of chapter 14 of title 35, United
12 States Code, is amended by adding at the end the follow-
13 ing new item:

 “158. Compulsory licensing of certain patents.”.

14 (2) Section 1295(a)(4) of title 28, United States
15 Code, is amended—

16 (1) by redesignating subparagraphs (B) and
17 (C) as subparagraphs (C) and (D), respectively; and

18 (2) by inserting after subparagraph (A) the
19 following:

20 “(B) the Board of Patent Appeals and
21 Interferences of the Patent and Trademark
22 Office under section 158(c)(1) of title 35;”.

1 **SEC. 3. APPLICABILITY.**

2 The amendments made by this Act shall apply with
3 respect to patents issued before, on, or after the date of
4 the enactment of this Act.

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